

**Summary Minutes of the Joint Anti-Infective Drugs Advisory Committee and
Nonprescription Drugs Advisory Committee Meeting**

April 2, 2012

**Location: DoubleTree by Hilton Washington DC/Silver Spring, 8727 Colesville Road, Silver
Spring, Maryland**

**All external requests for the meeting transcripts should be submitted to the CDER, Freedom
of Information Office.**

**These summary minutes for the April 2, 2012 joint meeting of the Anti-Infective Drugs
Advisory Committee and the Nonprescription Drugs Advisory Committee of the Food and
Drug Administration were approved on May 8, 2012.**

**I certify that I attended the April 2, 2012 joint meeting of the Anti-Infective Drugs Advisory
Committee and the Nonprescription Drugs Advisory Committee of the Food and Drug
Administration and that these minutes accurately reflect what transpired.**

_____/s/_____
Minh Doan, Pharm.D.
Designated Federal Officer, AIDAC

_____/s/_____
Thomas A. Moore, M.D., FACP
Committee Chairperson, AIDAC

The Anti-Infective Drugs Advisory Committee (AIDAC) and the Nonprescription Drugs Advisory Committee (NDAC) of the Food and Drug Administration, Center for Drug Evaluation and Research met on April 2, 2012 at the DoubleTree by Hilton Washington DC/Silver Spring, 8727 Colesville Road, Silver Spring, Maryland. Prior to the meeting, members and temporary voting members were screened and cleared for conflict of interest, and provided copies of the background material from the FDA and the Biomedical Advanced Research Development Authority. The meeting was called to order by Thomas A. Moore, M.D., FACP (Committee Chairperson, AIDAC); the conflict of interest statement was read into the record by LT Minh Doan, Pharm.D. (Designated Federal Officer, AIDAC). There were approximately 125 persons in attendance. There were three speakers for the Open Public Hearing session.

Issue: The committees met to provide advice on types of consumer studies needed to assess proper use of a MedKit containing doxycycline to be taken in the event of anthrax exposure. Issues such as the feasibility of an FDA-approved MedKit as a public health strategy, the role of personal MedKits, home stockpiling, and interfaces of home readiness with public health systems, were raised in the course of the discussions. The Biomedical Advanced Research and Development Authority proposed a possible plan for a step-wise development program for MedKits containing oral doxycycline hyclate.

Attendance:

Anti-Infective Drugs Advisory Committee Members Present (Voting):

Diane Cappelletty, Pharm.D., Sheldon L. Kaplan, M.D., Thomas A. Moore, M.D., FACP (Chairperson), Michael Neely, M.D., Kathleen Young (Consumer Representative)

Nonprescription Drugs Advisory Committee Members Present (Voting):

Steven C. Curry, M.D., Walid Gellad, M.D., M.P.H., Winifred A. Landis, R.Ph., C.D.E., Richard Neill, M.D., Ruther M. Parker, M.D., Marcus M. Reidenberg, M.D., FACP, Norma Martinez Rogers, Ph.D., R.N., FAAN (Consumer Representative), Leslie R. Walker-Harding, M.D.

Temporary Members (Voting):

Christopher Carpenter, M.D., FIDSA, Ruth S. Day, Ph.D., Brian Erstad, Pharm.D., Baruch Fischhoff, Ph.D., Robert Gray, Ph.D., Marie Griffin, M.D., Joan Hilton, Sc.D., M.P.H., Gavin Huntley-Fenner, Ph.D., Elaine Morrato, Dr.P.H., C.P.H, Christian Ockenhouse, M.D., Ph.D. (Patient Representative), Allen Vaida, Pharm.D., FASHP, Sidney Wolfe, M.D. (Consumer Representative to the Drug Safety and Risk Management Advisory Committee), T. Mark Woods, Pharm.D.

Acting Industry Representatives to the Committees (Non-Voting):

Patrick Robinson, M.D. (Acting Industry Representative to the Anti-Infective Drugs Advisory Committee), Lorna C. Totman, Ph.D., DABT (Acting Industry Representative to the Nonprescription Drugs Advisory Committee)

Centers for Disease Control and Prevention Speaker (Non-Voting, Presenting Only)

Linda Neff, Ph.D., M.S.P.H.

Department of Homeland Security Speaker (Non-Voting, Presenting Only)

Susan Collier-Monarez, Ph.D.

Minnesota Department of Health Speaker (Non-Voting, Presenting Only)

Ruth Lynfeld, M.D.

Associations' Speakers (Non-Voting, Presenting Only):

Robert R. Bass, M.D., FACEP (Institute of Medicine), James S. Blumenstock (Association of State and Territorial Health Officials), Marcie Bough, Pharm.D. (American Pharmacist Association), John Bradley, M.D. (American Academy of Pediatrics), Jack Herrmann, M.S.Ed., N.C.C. (National Association of County and City Health Officials), James J. James, M.D., Dr.P.H. (American Medical Association), Andrew T. Pavia, M.D., FAAP, FIDSA (Infectious Diseases Society of America), Christopher J. Topoleski (American Society of Health-System Pharmacists)

FDA Participants (Non-Voting):

Edward Cox, M.D., M.P.H., Katherine Laessig, M.D., John Alexander, M.D., M.P.H., Andrea Leonard-Segal, M.D., Barbara Cohen, M.P.A.

Anti-Infective Drugs Advisory Committee Members Not Present:

Paul G. Auwaerter, M.D., Archana Chatterjee, M.D., Ph.D., Melvin Weinstein, M.D.

Nonprescription Drugs Advisory Committee Members Not Present:

Neil J. Farber, M.D., Dorraine D. Watts, Ph.D., R.N.

Designated Federal Officer:

LT Minh Doan, Pharm.D.

Open Public Hearing Speakers:

Lawrence E. Tan (The Emergency Services Sector Coalition on Medical Preparedness), Matthew Minson, M.D. (Superior Energy Services, Inc.), Wayne Williams (Sharps Compliance, Inc.)

The agenda was as follows:

Call to Order and Introduction of Committees

Thomas A. Moore, M.D., FACP
Committee Chairperson, Anti-Infective Drugs Advisory Committee (AIDAC)

Conflict of Interest Statement

Minh Doan, Pharm.D.
Designated Federal Officer, AIDAC
CDER, FDA

FDA Presentations

Doxycycline MedKit Regulatory Background

John Alexander, M.D., M.P.H.
Clinical Team Leader
Division of Anti-Infective Products (DAIP)
Office of Antimicrobial Products (OAP),
Office of New Drugs (OND), CDER, FDA

Overview of Consumer Studies Potentially Applicable to the MedKit Development Program

Barbara Cohen, M.P.A.
Social Science Analyst
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV (ODE IV)
OND, CDER, FDA

**Centers for Disease Control and
Prevention Presentation**

Emergency MedKit Evaluation

**Linda J. Neff, Ph.D., M.S.P.H. (*presenting
via phone*)**

Senior Epidemiologist
Career Epidemiology Field Office
Office of Science and Public Health
Practice
Office of Public Health Preparedness and
Response
Centers for Disease Control and Prevention

Questions and Clarifications

**Minnesota Department of Health
Presentation**

Home MedKits for Volunteer Postal
Workers in a Cities Readiness Initiative
Plan: A Minnesota Perspective

Ruth Lynfield, M.D.
State Epidemiologist and Medical Director
Minnesota Department of Health

**Department of Homeland Security
Presentation**

Anthrax: An Enduring Terrorist Threat to
the Homeland

Susan Collier-Monarez, Ph.D.
Threat Characterization and Attribution
Branch Chief
Chemical and Biological Defense Division
Science and Technology Directorate
Department of Homeland Security

Sponsor's Presentation

Doxycycline Medkits for Public Health
Preparedness for an Anthrax Attack

**Biomedical Advanced Research and
Development Authority**

George W. Korch, Jr., Ph.D.
Senior Science Advisor
Office of the Assistant Secretary for
Preparedness and Response
Department of Health and Human Services

Questions and Clarifications

Associations' Presentations

Prepositioning Antibiotics for Anthrax

Robert R. Bass, M.D., FACEP
Executive Director
Maryland Institute for Emergency Medical
Services Systems
Chair, Committee on Prepositioned Medical
Countermeasures for the Public
Institute of Medicine

Perspective of the Infectious Diseases
Society of America

Andrew T. Pavia, M.D., FAAP, FIDSA
George and Esther Gross Presidential
Professor and Chief, Division of Pediatric
Infectious Diseases
University of Utah
Member, Board of Directors and Chair,
Pandemic Influenza and Bioemergencies
Task Force
Infectious Diseases Society of America

Associations' Presentations (cont.)

Local Health Department Perspectives on
MedKits

Jack Herrmann, M.S.Ed., N.C.C.
Senior Advisor & Chief
Public Health Preparedness
National Association of County and City
Health Officials

State Public Health's Perspective on
Medkits

James S. Blumenstock
Chief Program Officer
Public Health Practice
Association of State and Territorial Health
Officials

Observations on Countermeasures for
Anthrax

James J. James, M.D., Dr.P.H.
Director, Center for Public Health
Preparedness and Disaster Response
American Medical Association

Best Practices for Distribution of
Doxycycline: Public Health Impact and
Research Recommendations

Christopher J. Topoleski
Director, Federal Regulatory Affairs
American Society of Health-System
Pharmacists

American Pharmacist Association
Comments on MedKits for Anthrax
Exposure

Marcie Bough, Pharm.D.
Senior Director, Government Affairs
American Pharmacist Association

The American Academy of Pediatrics
Perspective on Stockpiling MedKits to be
used for Children as Anthrax Post-
Exposure Prophylaxis with Doxycycline

John Bradley, M.D.
Director, Division of Infectious Diseases
Rady Children's Hospital San Diego
Member, Anthrax Working Group, Disaster
Planning Advisory Council
American Academy of Pediatrics

Questions and Clarifications

Open Public Hearing

Charge to the Committees and
Committees Discussion

ADJOURN

Questions to the Committees:

1. **DISCUSSION:** Please comment on the public health implications of a prescription doxycycline MedKit intended for post-exposure prophylaxis for an anthrax counterterrorism event. Specifically address potential benefits and risks if a prescription MedKit were approved with the intention of home storage.

Members expressed several concerns regarding a prescription MedKit being approved with the intention of home storage. The development of drug resistance and unauthorized use were noted to be important risks to consider. In addition, several members commented on the issue of equity with regard to costs of the MedKits. Some members felt that an increased risk of an anthrax counterterrorism event would dictate the perceived benefit of a prescription MedKit for home storage. Several members suggested that MedKits should be available at defined points-of-distribution, such as community pharmacies, but not necessarily for individual home storage. However, members were more comfortable with the idea of home storage of MedKits by first-responders.

Please see the transcript for detailed discussion.

2. **DISCUSSION:**
 - a. Please comment on additions or modifications to the proposed and/or completed studies (e.g. label comprehension, palatability, simulated use, or additional studies) that would help to assess the risks and benefits. What types of additional studies would be helpful to assess how users would behave in a real-life situation?

Members suggested several different additional studies to assess how users would behave in a real-life situation. For label comprehension, members felt that simulating stress in the studies would provide useful information. In addition, members suggested testing comprehension of different label formats. Members also felt that it was important to test for comprehension among minority and low literacy populations. Other studies suggested included those to evaluate psychological effects of having such a MedKit available and to determine the current perspective on the risk of an anthrax counterterrorism event.

- b. What is a reasonable percentage of study subjects who should understand the various components of the label and/or be able to refrain from using the product for other uses?

Members commented that they would expect a high percentage of study subjects to understand the various components of the label. A suggestion of greater than 90% was provided.

Please see the transcript for detailed discussion.

3. **DISCUSSION:** The doxycycline MedKit proposal includes instructions for dosing children and adults who cannot swallow pills using the 100 mg tablets. Please comment on any additional recommended studies to evaluate the dosing instructions in this population.

Members felt that additional studies to evaluate the accuracy of the dosage when doxycycline tablets are prepared with instructions included a MedKit were warranted. Concerns were raised regarding effective drug provisions for young children. Members were also concerned with the complexity of the instructions as many steps were involved in preparation. Members noted that instructions should be explicitly clear and easily understood. It was also mentioned that units of measurement should be uniform. One study suggested comparing the accuracy of dosing when a liquid formulation was included in the MedKit versus preparation of a liquid formulation from a tablet.

Please see the transcript for detailed discussion.

4. **DISCUSSION:** Doxycycline is available in other dosages and as liquid formulations. Please discuss the pros and cons of the home preparation mixture versus other available formulations for use in a MedKit.

Members commented that having other dosage formulations (e.g. liquid) available in a MedKit could potentially reduce dosing errors associated with home preparation mixtures, but felt that cost would be an important factor. Members noted that oral tablets would be more cost-efficient, easier to store, and have a longer shelf-life.

Please see the transcript for detailed discussion.

The session adjourned at approximately 4:30 p.m.